REMARKS

This reply is filed in response to the final Office action dated April 22, 2009. Claims 1-7 are presented for examination.

Rejection under 35 U.S.C. §103(a)

The final Office action rejects claims 1-7 as obvious on two grounds, each of which is traversed below:

I

Claims 1, 2, and 4-7 are rejected as obvious from Fuke et al., EP 0997182 ("Fuke") in view of Nakagawa et al., U.S. Patent No. 5,071,887 ("Nakagawa") and Kozawa et al., U.S. Patent No. 6,605,218 ("Kozawa").

Independent claim 1 is discussed first. It recites a plurality of selectively permeable polysulfone-based hollow fiber membranes in which, among others, the content of a hydrophilic polymer (e.g., polyvinyl pyrrolidone) in the outer surface of the hollow fiber membrane is 25 to 50 mass %. According to the present specification, "When the content of the hydrophilic polymer of the outer surface of the membrane is less than 25 mass %, ... the compatibility of the membrane with the blood or the permeability thereof tends to lower. In case of the dried membrane, the priming capacity may become insufficient. ... When the content of the hydrophilic polymer on the outer surface of the membrane exceeds 50 mass %, endotoxins in the dialyzing fluid may more and more possibly infiltrate into the blood contact side of the membrane, which may induce side effects such as fevers, etc. Further, the hollow fiber membranes stick to one another due to the hydrophilic polymer present on the outer surface of the membranes while the membranes are being dried, and consequently, the module-fabricating workability may become poor." See paragraphs [0033] and [0035].

Fuke describes a polysulfone type blood-purifying membrane that has improved blood compatibility and separation properties, and has less poly(vinylpyrrolidone) eluting in the internal surface of the hollow fiber membrane. *See, e.g.*, the abstract. It also states that polyvinyl pyrrolidone (PVP, a hydrophilic polymer) "is contained in the range of 1 to 10% by weight in the [entire] hollow fiber membrane." *See, e.g.*, the abstract and paragraph [0017]. Further, Fuke states that

> "The important factor for the blood compatibility of the hollow fiber membranes is the hydrophilicity of the membrane surface which contacts blood, and in the PVP-containing polysulfone type hollow fiber membrane, the PVP concentration on the internal surface of the membrane is important. ... Accordingly, the surface PVP concentration in this invention is in the range of 30 to 45% [by weight], ..." *See* paragraph [0023]; emphases added.

It would have been apparent to one skilled in the art that Fuke describes using the internal surface of its hollow fiber membrane to contact blood and that the PVP content in the internal surface of its membrane is 30 to 45% by weight. Indeed, Fuke discusses the PVP content in the internal surface of its hollow fiber membrane in detail throughout all of paragraphs [0023]-[0025]. Thus, given that the PVP content in the entire membrane described in Fuke is at most 10% by weight, one skilled in the art would readily recognize that the PVP content in the outer surface of Fuke's membrane is significantly lower than 10% by weight, let alone 25 to 50 mass % as recited by claim 1. In other words, Fuke does not disclose or even suggest a membrane containing 25 to 50 mass % of a hydrophilic polymer in the outer surface, as recited by claim 1.

Neither Nakagawa nor Kozawa cures the deficiency in Fuke. Indeed, both references are entirely silent on a membrane containing 25 to 50 mass % of a hydrophilic polymer in the outer surface, as recited by claim 1.

Thus, claim 1 would not have been obvious from Fuke in view of Nakagawa and Kozawa. As claims 2 and 4-7 depend from claim 1, they would also not have been obvious from Fuke in view of Nakagawa and Kozawa.

II

Claim 3 is rejected as obvious from Fuke in view of Nakagawa and Van't Hoft et al., U.S. Patent No. 5,514,413 ("Van't Hoft").

Claim 3 incorporates the features of claim 1, which recites membranes having 25 to 50 mass % of a hydrophilic polymer in the outer surface recited in claim 1. As discussed above, neither Fuke nor Nakagawa discloses or even suggests such a membrane.

Van't Hoft does not cure the deficiencies in Fuke and Nakagawa. Further, Van't Hoft describes fabricating composite membranes by coating a porous substrate with a solution of selective polymer. *See, e.g.*, the abstract. However, Van't Hoft is entirely silent on a membrane having 25 to 50 mass % of a hydrophilic polymer in the outer surface.

Thus, claim 3 would not have been obvious from Fuke in view of Nakagawa and Van't Hoft.

In addition, claims 3 would not have been obvious from Fuke in view of Nakagawa and Van't Hoft on an additional, independent ground.

Claim 3 recites that the porosity of the outer surface of the hollow fiber membrane is 8 to 25%. The Office action asserts that "FUKE does not appear to explicitly disclose the specific range of the porosity on the outer surface. However, VAN'T HOFT discloses a surface porosity of 1 to 20% (Column 3, Lines 6-7)." *See* the office action, page 5, last paragraph. As discussed in Applicants' reply filed on February 9, 2009, it would not have been obvious to combine Fuke with Van't Hoft at least because the membrane described in Van't Hoft (i.e., a gas separation membrane) has a different purpose from that described in Fuke (i.e., a blood-purifying membrane) and replacing the processes described in Fuke with that described in Van't Hoft to achieve a porosity of 8 to 25% in the outer surface of a membrane would defeat the intended purpose of the membrane described in Fuke. *See* pages 9 and 10.

Further, even if it might have been obvious to combine Van't Hoft with Fuke and Nakagawa (which Applicants do not concede), the combination would still not have been the membranes of claim 3. Specifically, the final Office action asserts that

> "FUKE discloses that the size of the pores in each layer and the thickness of the layers influence the fractionation properties of the membrane (Para. 37-38), which are result effective variables in determining the porosity of layers (i.e., outer surface); therefore it would be obvious to a person having ordinary skill to optimize the porosity as taught by VAN'T HOFT." *See* the paragraph bridging pages 7 and 8.

However, Fuke and Van't Hoft fail to recognize the criticality of a porosity of 8% to 25% in the outer surface of a membrane. According to the specification,

> "the porosity of the outer surface of the hollow fiber membrane is preferably 8 to 25%, ... in order to impart the above described characteristics to the membrane. When the porosity and average pore area are too small [e.g., smaller than 8%], ... the module-fabricating workability tends to lower, since the hollow fiber membranes are stuck to one another because of the hydrophilic polymer on the outer surfaces of the membranes, while the membranes are being dried. .... when the porosity and the average pore area are too large [e.g., higher than 25%], the

percentage of void of the hollow fiber membrane becomes too high, and the burst pressure tends to lower." *See* paragraph [0082].

In other words, the specification teaches that a porosity of 8% to 25% is critical in achieving a suitable module-fabricating workability while still maintaining a proper burst pressure for the hollow fiber membranes. By contrast, neither Fuke nor Van't Hoft recognizes this criticality. Indeed, as discussed above, Fuke focuses on the PVP content in the internal surface, not the outer surface, of it membrane. Thus, even if it might have been obvious to combine Fuke and Van't Hoft (which Applicants do not concede), one skilled in the art would at most modify the porosity of the internal surface of Fuke's membrane, but would not have been motivated to modify the outer surface of Fuke's membrane, let alone modifying the porosity of the outer surface of Fuke's membrane to 8% to 25%, as recited by claim 3.

For the reasons set forth above, claim 3 would not have been obvious from Fuke in view of Nakagawa and Van't Hoft on this additional, independent ground.

Double patenting rejections

Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over (1) claims 1-9 of co-pending Application No. 10/559,544 and (2) claims 1-6, 16, and 17 of co-pending Application No. 10/599,167. Applicants request that these two rejections be held in abeyance until claims 1-7 are otherwise in condition for allowance.

CONCLUSION

Applicants submit that the obviousness rejections asserted by the final Office action have been overcome.

Any circumstance in which Applicants have: (a) addressed certain comments of the Examiner does not mean that Applicants concede other comments of the Examiner; and (b) made arguments for the patentability of some claims does not mean that there are not other good reasons for the patentability of those claims and other claims.

Please apply any charges to deposit account 06-1050, referencing Attorney's Docket No. 19461-0004US1.

Respectfully submitted,

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